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FDA grants Fast Track Designation for SPI-1005 in the Treatment of Meniere's Disease

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SEATTLE, Sept. 18, 2019 /PRNewswire/ -- Sound Pharmaceuticals is pleased to announce that the FDA's Division of Neurology Products has granted its request for Fast Track Designation (FTD) involving SPI-1005 in the treatment of Meniere's Disease (MD). FTD applies to serious conditions where the potential to address unmet medical need has been demonstrated. SPI's clinical data from two completed multi-center, randomized, placebo-controlled studies (Phase 1b and Phase 2b clinical trials) were the basis for the designation, and showed that oral delivery of SPI-1005 for 21 or 28 days improved tinnitus and restored sensorineural hearing loss in patients affected by MD. FTD allows for the expedited development of SPI-1005 involving more frequent meetings with the FDA, rolling reviews, and the potential for priority review at the filing of New Drug Application (NDA). SPI has an End-of-Phase 2 Meeting scheduled with the FDA to discuss the pivotal Phase 3 study design and additional data required for NDA filing. "This is a major regulatory milestone for our most advanced clinical program to date," said Jonathan Kil, MD, Co-Founder and CEO.

About the SPI-1005 Phase 1b and Phase 2b trials

The Phase 1b and Phase 2b trials randomized 39 and 126 subjects, respectively to placebo or active doses of SPI-1005, and treated for 21 or 28 days, respectively. Clinically relevant improvements in sensorineural hearing loss were determined using pure-tone audiometry (PTA) and the words-in-noise test (WINT), two validated measures of hearing sensitivity and specificity administered by an audiologist. Patient reported tinnitus and vertigo were assessed using the Tinnitus Functional Index (TFI) and Vertigo Symptoms Scale (VSS). Improvement in PTA/WINT and TFI/VSS scores from baseline were compared between SPI-1005 dose groups and the placebo group.

In the Phase 2b study, clinically relevant improvements were observed in low frequency hearing by PTA and WINT scores at 8 weeks after the start of study drug when compared to placebo. The percentage of subjects showing significant auditory improvements using PTA (≥10 dB gain at one

low frequency) in the 400 mg dose group rose from 47% at 4 weeks to 61% at 8 weeks, while the percentage using WINT (≥20% increase in word recognition) rose from 57% at 4 weeks to 68% at 8 weeks. Additionally, SPI-1005 treatment reduced tinnitus perception or tinnitus loudness (TL) by a statistically significant difference (p-value <0.05 using Fisher's Exact test) when compared to placebo. Reductions in TL averaged 1.4 pts in the 400 mg group vs 0.7 pts in the placebo group (30% reduction vs 10% reduction, p<0.02). These Phase 2b data confirmed an initial finding of the Phase 1b data, that SPI-1005 can lower tinnitus loudness by clinically relevant levels. These improvements in auditory function further support the use of SPI-1005 to treat sudden idiopathic hearing loss, noise-induced hearing loss, and age-related loss where sensorineural hearing loss and tinnitus are prominent features.

About Meniere's Disease (MD)

MD is diagnosed by episodic vertigo, fluctuating hearing loss, and intermittent or constant tinnitus, and is thought to be due to a swelling or inflammation of the inner ear. The auditory symptoms of hearing loss (at low frequencies below 2000 Hz) and tinnitus (roaring/ringing) often involve one ear. MD patients are typically diagnosed between 40-65 years of age. As patients age, the hearing loss and/or tinnitus become progressively worse. For the definitive diagnosis of MD, new American Academy of Otolaryngology-Head & Neck Surgery guidance requires documentation of ≥30 dB of low frequency hearing loss in at least one ear using PTA. The upper limit of normal hearing sensitivity is 20 dB, and every 10 dB loss of hearing is considered clinically relevant. Loss of word recognition especially in noisy environments or when tinnitus is present is common in MD, and other forms of hearing loss. Currently, there are no FDA approved drug treatments for MD, or any other inner ear disease. MD is managed with low salt diets, thiazide diuretics, and oral or locally injected steroids. Unfortunately, this type of medical management or standard of care has not been proven to be effective.

About SPI-1005

SPI-1005 is an investigational new drug that contains ebselen, a small molecule that is a new chemical entity, or NCE, under FDA classification. Ebselen is a selenorganic compound that mimics and induces glutathione peroxidase (GPx) activity and represents a novel class of anti-inflammatory. GPx activity is critical to several cell types and tissues in the

inner ear, retina, brain, lung and kidney, and is often reduced during exposures to environmental insults. Loss of GPx activity has been shown to result in sensorineural hearing loss in multiple animal models. SPI-1005 is given orally and is being tested in several neurotologic indications including noise induced hearing loss and tinnitus, and two types of ototoxicity (hearing loss, tinnitus, dizziness or vertigo): due to aminoglycoside antibiotics (such as tobramycin) and due to platinum-based chemotherapy. In earlier clinical trials, SPI-1005 demonstrated strong proof-of-concept data supporting the potential treatment in preventing and treating noise induced hearing loss and Meniere's disease.

About Sound Pharmaceuticals

A privately held biotechnology company is testing SPI-1005 under four active Investigational New Drug Applications involving several neurotologic indications, including an ongoing Phase 2 clinical trial in Cystic Fibrosis patients receiving IV tobramycin for the treatment of pulmonary exacerbation. The company is also studying bipolar disorder in collaboration with the University of Oxford, in a proof-of-concept Phase 2 clinical trial where the novel anti-inflammatory and neuroprotective properties of SPI-1005 are being tested in active hypomania. That study is now complete and will disclose top-line data later this year.

Details of the SPI-1005 clinical trials can be viewed online at www.clinicaltrials.gov, or by visiting www.soundpharma.com.

View original content:http://www.prnewswire.com/news-releases/fda-grants-fast-track-designation-for-spi-1005-in-the-treatment-of-menieres-disease-300920456.html

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